K010306
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OCT - 3 2001

510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-0818 Fax
Contact:	Jeanne M. Cush Senior Regulatory Affairs Associate
Date Prepared:	January 24, 2001

B. Trade Name: Medcomp Excell Split Tip Catheter
Common Name: Hemodialysis Catheter, Implanted
Classification: 78 MSD
C.F.R. Section: 876.5540

C. Predicate Device:

K913468 Cook Uldall Double Lumen Hemodialysis Catheter

K981125 Medcomp Tesio Catheter
K972207 Medcomp Ash Split-Cath
(for kit components)

D. Device Description:

The Medcomp Excell Split Tip Catheter is a 15F polyurethane, double lumen catheter used to remove and return blood through two-segregated lumen passages. The outer lumen is oval with cylindrical shaped inner lumens which are split at the distal tips. The distal venous lumen extends beyond the arterial lumen to reduce recirculation. The fixed polyester cuff allows for tissue ingrowth for long term placement.

The lumens are connected to the extensions via a low profile, soft pliable hub with suture wing. The Medcomp Lock Right Adapters serve as the arterial and venous extensions and are identified by red and blue luer connectors and clamps. Priming volume information is printed on the clamps for ease in identification.

E. Intended Use:

The Medcomp Excell Split Tip Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein. Alternate insertion site is the subclavian vein as required.

F. Comparison to Predicate Device:

The technological characteristics of the Excell Split Tip Catheter are substantially equivalent to the predicate devices in terms of intended use, insertion method, anatomical location, design, performance, labeling, manufacturing process and method of sterilization.

The material formulation of the Excell Split Tip is different than both of the predicate devices, as is the implantable lengths and cuff location. The Excell Split Tip offers an alternative insertion method to reduce air embolism during insertion. Details on this technique is included in Section 2 of this submission.

G. Performance Data:

In Vitro performance data for the Medcomp Excell Split Tip Catheter, including tensile strength, joint strength, leakage, recirculation and flow performance demonstrate that this device is substantially equivalent to legally marketed devices intended for hemodialysis and apheresis treatments. Additional testing on the proposed device includes flexural testing of the catheter extension, biocompatibility and chemical exposure testing.

Clinical studies were not deemed necessary since in-vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2001

Ms. Jeanne M. Cush
Senior Regulatory Affairs Associate
MedComp®, Inc.
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K010306
Trade/Device Name: MedComp - Excell Hemodialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: August 23, 2001
Received: August 27, 2001

Dear Ms. Cush:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: Medcomp Excell Split Tip Catheter

Indications for use:

THE MEDCOMP EXCELL SPLIT TIP CATHETER IS INDICATED FOR USE IN ATTAINING LONG-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS.

IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN.

ALTERNATE INSERTION SITES INCLUDE SUBCLAVIAN VEIN AS REQUIRED.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K010306

(Optional Format 1-2-96)